

Medi-Cal Pharmacy Program

WHOLESALE SELLING PRICE
(WSP)

INFORMATION MEETING

APRIL 8, 2005

Introductions

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- **Katherine Ahrens, Pharm.D.**

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Welcome

- Thank you for attending
- Discussion Reminder

Participants are reminded that we are in a group setting and must consider the potential for antitrust implications when engaging in discussion.

- Why we are here
 - Welfare & Institutions Code Section 14105.45

OVERVIEW

- Background
- California Statute
- Discussion of Wholesaler Selling Price
- Reporting format and attestation
- Implementation timeline
- Next steps
- Questions

Background

- WSP – Wholesaler Sales Price
- First added to CA statute in 2002
- Language was “placeholder”
- Conveyed Medi-Cal’s intent
- Response to Qui Tam lawsuits on federal false claiming issues
- “Toothless” – did not compel wholesalers to comply

Section 14105.45

- Budget Health Trailer for 2004
- Refined language on WSP
- Provides mandatory penalty for wholesaler non-compliance

Current language:

14105.45(b)(3)(E): The failure of a wholesaler to report wholesale selling prices pursuant to subparagraph (C) of paragraph (3) of subdivision (b) **shall** result in the director denying payment for **all** drugs supplied by that wholesaler to Medi-Cal program beneficiaries. The denial of payment shall be effective no sooner than 30 days after notifying pharmacy providers of the change through a provider bulletin.

DHS plans to change this language from mandatory (shall) to permissive (may).

Current language:

14105.45(b)(3)(A): The department shall base the MAIC on the mean of the wholesale selling prices of drugs generically equivalent to the particular innovator drug that are available in California from wholesale drug distributors **selected** by the department.

14105.45(b)(3)(A): The department shall notify each **selected** wholesale drug distributor, in writing, that the wholesale drug distributor has been identified as a source of wholesale pricing information.

DHS will be selecting **all** wholesalers and will change statute accordingly.

WSP Defined

(11) "Wholesale selling price" means the weighted (by unit volume) mean price, including discounts and rebates, paid by a pharmacy to a wholesale drug distributor.

- CA statute
 - May include “class of trade” reporting
- Input from all concerned

W&I Code, Section 14105.45(a)(11) – on slide

14105.45(b)(3)(C): Wholesale drug distributors notified pursuant to subparagraph (B) shall, no later than 30 days after the end of each month, and in a format determined by the department, provide to the department the wholesale selling price of all legend and nonlegend drugs **sold to pharmacies**.

DHS is giving consideration to changing statute to include class of trade reporting. Need test data to make final determination.

WSP Calculation

- Provider concern with inclusion of non-retail entities
- Class-of-trade potential
- DHS will issue guidance as it proceeds

14105.45(b)(3)(C): Wholesale drug distributors notified pursuant to subparagraph (B) shall, no later than 30 days after the end of each month, and in a format determined by the department, provide to the department the wholesale selling price of all legend and nonlegend drugs **sold to pharmacies**.

WSP reporting requirement includes OTC drugs.... It does not include sales to non-pharmacy entities (e.g. grocery stores).

DHS giving consideration to changing statute to include class-of-trade reporting.

Which Products

- TEST – Is it sold in California?
- No restrictions on product class or dosage form
- Includes all drugs regardless of federal rebate status
- What about vaccines?

14105.45(b)(3)(A): The department shall base the MAIC on the mean of the wholesale selling prices of drugs generically equivalent to the particular innovator drug that are available in **California** from wholesale drug distributors selected by the department.

May change statute to include vaccines.

Reporting

- Based on the 11-digit NDC (same as reimbursement)
- Certification will be required – by whom and frequency has yet to be determined
- Reported to DHS or designated agent
- Electronic process
- Monthly reporting
 - Wholesale drug distributors notified pursuant to subparagraph(B) shall, no later than 30 days after the end of each month, and in a format determined by the department, provide to the department the wholesale selling price of all legend and nonlegend drugs sold to pharmacies.

WHOLESALE SELLING PRICE (WSP) LAYOUT

Header
Wholesaler name
Wholesaler address
Contact person
Phone number
E-mail address
DATE
NUMBER OF LINE ITEMS REPORTED

**SUGGESTED
LAYOUT**

NDC	Manufacturer Description (Labeler Description)	Product Description (Label Name)	Package Size	WSP per unit	Unit of Measure	Start date of WSP reporting period	End date of WSP reporting period
11 digit NCPDP formatted code	alpha-numeric, 60 characters	alpha-numeric, 60 characters	numeric 12 characters 9(8).9(3)	numeric 12 characters 9(6).9(5)	MUST follow NCPDP Billing Unit Standard	First day of reporting quarter	Last day of reporting quarter
alpha-numeric 11 characters	only used in QCs	only used in QCs	MUST follow NCPDP Billing Unit Standard	MUST follow NCPDP Billing Unit Standard		numeric 8 characters, YYYYMMDD	numeric 8 characters, YYYYMMDD

Full file each time NDC's that have an effective date (e.g., NOT zero date/zero price). If prices go to zero, we do then need the date+zero price record.

Delimited text file is best (no Excel, no PDF) with fixed length fields (using Standard Product terms, "RELD" not "RELDV" format)

Electronic format (e.g. download or CD)

Headers are not useful to us. And if we have a standard format, then we know what's in each column.

Compliance

- Statute requires compliance or....
 - The failure of a wholesaler to report wholesale selling prices pursuant to subparagraph (C) of paragraph (3) of subdivision (b) **shall** result in the director denying payment for all drugs supplied by that wholesaler to Medi-Cal program beneficiaries.
- ALL WHOLESALERS
- Mandatory
- Errors – Can WSP be corrected?
 - May depend on when correction occurs

Current language:

14105.45(b)(3)(A): The department shall base the MAIC on the mean of the wholesale selling prices of drugs generically equivalent to the particular innovator drug that are available in California from wholesale drug distributors **selected** by the department.

14105.45(b)(3)(B): The department shall notify each **selected** wholesale drug distributor, in writing, that the wholesale drug distributor has been identified as a source of wholesale selling price information.

DHS intends to change statute from “select” to “all”.

How is WSP used

- The department shall base the MAIC on the mean of the wholesale selling prices of drugs generically equivalent to the particular innovator drug that are available in California from wholesale drug distributors selected by the department.
- DHS will look at multiple factors when setting a pharmacy rate

DHS will meet with pharmacy providers/representatives/organizations when considering changes to the pharmacy reimbursement rate.

How is WSP used

- Protection of WSP confidentiality

All pricing information reported by a wholesale distributor to the department pursuant to this section shall be considered confidential and corporate proprietary information and shall not be subject to disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

- Reverse engineering from Selling Price
 - Unknown at this time
- WSP will not be used in calculating rebates unless federal statute changes to do so

W&I Code, Section 14105.45(b)(3)(F) – **on slide**

•Should it be determined that WSP will be used in the pharmacy reimbursement rate, the department will seek to structure the reimbursement calculation so that it cannot be reverse engineered to get to the WSP.

How is WSP used

- WSP may be used for other programs in the future
- Will affect both Workers Compensation and SB393 since both programs point to Medi-Cal reimbursement rates

Other Issues

- State plan already reflects WSP use
- DHS will submit a State Plan Amendment if needed
- Dispensing fee – change may or may not occur – will be discussed with providers
- Contracts – not needed, but may still occur to memorialize finer points not in statute

Timeline



Projected timeline for full implementation of WSP reporting: January 2007

Some factors influencing timeline:

- Possible need for systems changes
- Statutory changes - e.g. modification of W&I Code, Section 14105.45(b)(3)(A)-(C) since it is the Department's intention that all drug wholesalers who sell drug in California report WSP; possible modification of W&I Code, Section 14105.45(b)(3)(E) to change the WSP reporting penalty requirement from mandatory to permissive.
- Possible need for state plan amendment
- Need to collect test data from wholesalers to facilitate development of final guidance for WSP calculation.
- Updated information will be posted on this website as it becomes available.

Next Steps

- Disseminating information
 - Website: <http://www.dhs.ca.gov/pharmacy>
 - Email for additional questions: WSP@dhs.ca.gov
- Individual meetings – only if absolutely needed for proprietary issues that cannot be handled by correspondence
- Follow-up meeting in the future
 - Future meeting will make telecommunications an option

Website address: <http://www.dhs.ca.gov/pharmacy>

E-mail address: WSP@dhs.ca.gov (non-WSP related email will not be responded to, please use **P.O. Box 997417, MS 4604, Sacramento, CA 95899-7417** for non-WSP correspondence.)

Next Steps

- Meeting with Pharmacy Providers
- Follow-up statutory changes
- State Plan changes if needed

We anticipate meeting with each wholesaler individually.

QUESTIONS